



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,569	10/11/2006	Alexander J. Pallenberg	600057.438USPC	2653

500 7590 08/05/2010
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
----------	--------------

1654

MAIL DATE	DELIVERY MODE
-----------	---------------

08/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,569	Applicant(s) PALLENBERG ET AL.	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/9/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

DETAILED ACTION

Applicant's arguments, amendments are filing of the RCE are acknowledged.

Election/Restrictions

As noted previously, Applicant's election without traverse of the following 3 species:

- 1) flourophore or photosensitizer (CHLORIN); bound to any agent that function as a
- 2) quenching agent (BETA CAROTENE/CAROTENOID); bound to any agent that can function as a
- 3) targeting moiety (ANTIBODY).

in the reply filed on 5/4/09 is acknowledged.

Claim Rejections - 35 USC § 103-Vacated based on Argument/Amendment

Claim Rejections - 35 USC § 112 2nd-Omission of Essential Elements

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The Amended Claimed Invention

Independent claim 1, now amended, recites:

1. (Original) A conjugate, comprising: a fluorophore or a photosensitizer, a quenching agent; and a targeting moiety, wherein: the fluorophore or the photosensitizer

Art Unit: 1654

is linked to the quenching agent and the targeting moiety in such a way that activation of the fluorophore or the photosensitizer is quenched until the targeting moiety is bound to a target, whereupon the quenching agent [moves away from the photosensitizer] –**remains linked** but is displaced from interaction-permissive energy transfer conformation with the photosensitizer--, enabling activation of the photosensitizer upon irradiation with light of a suitable wavelength.

The omitted elements is: **the non-cleavable linker**. [As opposed to a cleavable linker, as taught by the art].

Interview-June 8, 2010

In the June 8, 2010 interview, Applicant's Representative stated that Applicant's found the linker is the element provides the essential advantage of the invention.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: An interview was scheduled to discuss the outstanding 35 USC 103 under a single reference to Singh. Applicant's position is that the reference does not suggest or provide motivation that would have made predictable the present invention. In Singh the PS2 (photosensitizing agent) must be released into solution to be detected with their microfluidic device. Whereas in the present invention, Applicant's PS2 must remain at the targeting site and NOT move into solution to be active.

Applicant's essential finding is binding the targeting site causing displacement of the quenching agent, and then allows the photosensitizing agent to work targeting site.

How Applicant was able to carry this out, was via a linker that allows for quenching to be sterically displaced from the photosensitive WITHOUT being cleaved.

The prior art does link the quenching agent to the targeting agent, but via a CLEAVABLE linker.

Art Unit: 1654

So the key element of the present invention is the sterically displaceable linker, that generates the unexpected results. Namely, the conjugate can be injected and be entirely inactive until it reaches the targeting site.

Furthermore, Singh is drawn to release of a photosensitizing agent into solution for detection by a device. They do not use it as a targeting conjugate.

Applicant will be responding to the outstanding rejection, in line with the arguments set forth above in the interview. The Examiner acknowledges the above and will undertake a full review and updated search of the art, once the response is received.

Applicant has only amended the claims to generally say the quenching agent "remains linked". Linked by what? One or more non-cleavable linkers are essential elements of the invention. Absent evidence to the contrary within the description or by affidavit with evidence of what the art knew made up the class of cleavable linkers v. non-cleavable linkers. SUCH THAT, such a non-cleavable linker is not e.g. too bulky to not allow the conjugate to carry out its function.

Without this amendment or evidence, the claims are not distinctly claimed, leaving a gap and indefiniteness as to the essential element of the invention.

Thus, in response hereto, unless such evidence can be provided, it is suggested that Applicant expressly claim the single linker or the Markush group of linkers that he has found work as non-cleavable linkers, rather than the cleavable linkers found in the art. The non-cleavable linker being the essential element that enables the claimed inventions unexpected results over the prior art of record.

Art Unit: 1654

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960.

The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA 7/31/10

/Maury Audet/
Primary Examiner, Art Unit 1654